European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 12 June 2008
Doc. Ref. EMEA/210293/2008

EMEA PUBLIC STATEMENT ON THE SUSPENSION OF THE MARKETING AUTHORISATION FOR OPTISON (perflutren) IN THE EUROPEAN UNION

On 18 May 1998, the European Commission granted a marketing authorisation valid throughout the European Union for the medicinal product Optison (perflutren). Optison is a diagnostic agent for the enhancement of contrast effect in echocardiography investigations.

On 12 June 2008, the European Commission issued a Decision to suspend the marketing authorisation for Optison. This confirmed the European Medicines Agency's (EMEA's) recommendation made in March 2008.

Of note, Optison is currently not marketed in the European Union (EU) and European Economic Area (EEA).

In the context of the re-assessment of the benefit-risk balance for Optison during the second renewal procedure of the product's marketing authorisation, the EMEA's Committee for Medicinal Products for Human Use (CHMP) noted that the marketing authorisation holder (MAH) was not able to provide an authorised importer for Optison to ensure the supply of the medicinal product in the European market and prove good manufacturing practice (GMP) compliance at the manufacturing site in the United States of America (USA). The CHMP therefore recommended that the marketing authorisation for Optison be suspended.

For further information, please contact:
Noël Wathion
Head of Unit, Post-Authorisation Evaluation of Medicines for Human Use
Tel: +44 20 7418 8411/Fax: +44 20 7418 8668